K030522

SEP 12 2003

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

510(k) SUMMARY
FOR
Clear Care Cleaning and Disinfecting Solution

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley Telephone No: 678-415-3897

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: Clear Care Cleaning and Disinfecting Solution

3. **Predicate Device(s)**

AOSEPT Clear Care Cleaning and Disinfecting Solution
Opti-Free Express Multipurpose Solution

4. **Description of the Devices**

Clear Care Cleaning and Disinfecting Solution is an aqueous solution contains hydrogen peroxide 3% (stabilized with phosphoric acid), sodium chloride, a phosphate buffer system and a non-ionic surfactant.

5. **Indications for Use**

Clear Care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) contact lenses as recommended by your eye care practitioner.

6. **Reason for 510(k) Submission**

The purpose of this 510(k) submission is to revise the package insert for Clear Care to include the following statements:

- Clinical studies show that Clear Care may provide better comfort to contact lens wearers who have experienced discomfort from preserved multipurpose solutions that do not contain peroxide.
- Clear Care provides lasting comfort for all day lens wear.

7. **Description of Safety and Substantial Equivalence**

Non clinical test and results:
Solution remain unchanged from those cleared under Premarket 510(k) Notification's K003345 and K013521.

Clinical Results:
A multicenter comparision of AOSept Clear Care and multipurpose contact lens care systems.
The primary objective of this study was to compare patient dryness and discomfort symptoms found with using several currently marketed multipurpose solutions versus AOSept Clear Care. In the study, subjects were evaluated for the frequency of dryness,

the intensity of dryness, symptoms, comfort and vision. The study was an open label, multi-center study, and was completed at 18 eyecare offices throughout the United States. To reduce bias in the results, patients were masked by not disclosing the name of the sponsor. A total of 148 patients were enrolled in the study.

Conclusion: Among previous multipurpose users, significant improvements were found after switching to AOSept Clear Care. The improvements in comfort were found in each measure of comfort in this study: frequency and intensity of dryness, during the day and end of the day comfort all showed significant improvements.

AOSept Improved UKClinical Trial R-162-C-002

This was a one-month prospective, randomised, masked, contra-lateral with crossover clinical trial of 182 subjects. There were two arms to the trial - 100 subjects using Clear Care with one control product and 75 subjects using Clear Care with a currently marketed multipurpose solution as the control.

Conclusion - The data from this study demonstrated that Clear was substantially equivalent to the control multipurpose solution in terms of hours of lens wearing time and hours of comfortable wearing time.

8. **Substantial Equivalence**

Clear Care Cleaning and Disinfection Solution is substantially equivalent to the selected predicate products for cleaning, disinfecting, daily protein removal and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

CIBA Vision Corporation
c/o Steven Dowdley
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K030522
Trade/Device Name: Clear Care Cleaning and Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: June 19, 2003
Received: June 23, 2003

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: Clear Care Cleaning and Disinfecting Solution

Indications for Use:
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☒

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K030522